

AR201-13289B

I U C L I D

D a t a S e t

Existing Chemical	ID: 99-08-1
CAS No.	99-08-1
EINECS Name	3-nitrotoluene
EINECS No.	202-728-6
TSCA Name	Benzene, 1-methyl-3-nitro-
Molecular Formula	C7H7NO2

Producer Related Part

Company:	Bayer Corporation
Creation date:	21-OCT-1999

Substance Related Part

Company:	Bayer Corporation
Creation date:	21-OCT-1999

Memo: Bayer Corporation

Printing date:	15-AUG-2001
Revision date:	
Date of last Update:	15-AUG-2001

Number of Pages: 55

Chapter (profile):	Chapter: 1, 2, 3, 4, 5, 7
Reliability (profile):	Reliability: without reliability, 1, 2, 3, 4
Flags (profile):	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

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1. General Information

Date: 17-APR-2001

ID: 99-08-1

1.0.1 OECD and Company Information

Type: lead organisation
Name: American Chemistry Council, Monocyclic Aromatic Amines and Nitro Aromatics (MAANA) Panel
Street: 1300 Wilson Boulevard
Town: 22209 Arlington, VA
Country: United States
Phone: 703-741-5600
Telefax: 703-741-6091

Flag: Critical study for SIDS endpoint
17-APR-2001

Type: cooperating company
Name: Bayer Corporation
Street: 100 Bayer Road
Town: PA 15205-9741 Pittsburgh
Country: United States

Flag: Critical study for SIDS endpoint
01-JUN-2000

Type: cooperating company
Name: First Chemical Corporation
Street: 1001 Industrial Road
Town: 39568 Pascagoula, MS
Country: United States

Flag: Critical study for SIDS endpoint
01-JUN-2000

Type: cooperating company
Name: Buffalo Color Corporation
Street: 100 Lee Street
Town: 14210 Buffalo, NY
Country: United States

Flag: Critical study for SIDS endpoint
01-JUN-2000

1.0.2 Location of Production Site

-

1.0.3 Identity of Recipients

-

1.1 General Substance Information

-

1. General Information

1.1.0 Details on Template

-

1.1.1 Spectra

-

1.2 Synonyms

-

1.3 Impurities

-

1.4 Additives

-

1.5 Quantity

-

1.6.1 Labelling

-

1.6.2 Classification

-

1.7 Use Pattern

-

1.7.1 Technology Production/Use

-

1.8 Occupational Exposure Limit Values

-

1.9 Source of Exposure

-

1.10.1 Recommendations/Precautionary Measures

-

1.10.2 Emergency Measures

-

1. General Information

1.11 Packaging

-

1.12 Possib. of Rendering Subst. Harmless

-

1.13 Statements Concerning Waste

-

1.14.1 Water Pollution

-

1.14.2 Major Accident Hazards

-

1.14.3 Air Pollution

-

1.15 Additional Remarks

-

1.16 Last Literature Search

-

1.17 Reviews

-

1.18 Listings e.g. Chemical Inventories

-

2. Physico-chemical Data

Date: 17-APR-2001
ID: 99-08-1

2.1 Melting Point

Value: 15.5 degree C
Decomposition: no
Sublimation: no
Method: other: handbook value
GLP: no data
Testsubstance: other TS: m-nitrotoluene; purity not noted
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (1)

Value: 15.5 degree C
Method: other: Handbook value
Testsubstance: other TS: m-nitrotoluene; purity not noted
Reliability: (2) valid with restrictions
17-APR-2001 (2)

Value: ca. 16 degree C
Method: other: DIN 51556
Reliability: (2) valid with restrictions
17-APR-2001 (3)

2.2 Boiling Point

Value: 232 degree C at 1013 hPa
Decomposition: no
Method: other: handbook value
GLP: no data
Testsubstance: other TS: m-nitrotoluene; purity not noted
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (1)

Value: 231 degree C at 1013
17-APR-2001 (3)

2.3 Density

Type: density
Value: 1.1581 g/cm3 at 20 degree C
Method: other: Handbook value
GLP: no data
Testsubstance: other TS: m-nitrotoluene; purity not noted
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (1)

2. Physico-chemical Data

Date: 17-APR-2001
ID: 99-08-1

Type: density
Value: 1.16 g/cm3 at 20 degree C
Method: other: Handbook value
Source: Bayer AG Leverkusen
Reliability: (2) valid with restrictions
01-JUN-2000 (2)

2.3.1 Granulometry

-

2.4 Vapour Pressure

Value: 10 hPa at 89.7 degree C
Method: other (measured): handbook value
GLP: no data
Test substance: other TS: m-nitrotoluene; purity not noted
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (4)

Value: 1.33 hPa at 50.2 degree C
Method: other (measured)
GLP: no
01-JUN-2000 (5)

Value: .199 hPa at 20 degree C
Source: Bayer AG Leverkusen
01-JUN-2000 (6)

2.5 Partition Coefficient

log Pow: 2.45 at 25 degree C
Method: other (measured)
Year:
GLP: no
Test substance: other TS: m-nitrotoluene; purity not noted
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (7)

log Pow: 2.358 at 20 degree C
Method: other (calculated): KOWWIN Program (v1.65)
Year: 1999
GLP: no
Test substance: other TS: molecular structure
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (8)

2. Physico-chemical Data

Date: 17-APR-2001
ID: 99-08-1

log Pow: 2.43
Method: other (calculated)
Year:
17-APR-2001 (9)

log Pow: 2.5
Method: other (calculated): Leo, Hansch
Year:
17-APR-2001 (6)

2.6.1 Water Solubility

Value: 283.5 mg/L at 25 degree C
Qualitative: moderately soluble (>100-1000 mg/L)
Method: other: WS-KOWv1.36
Year: 1999
Testsubstance: other TS: molecular structure
Reliability: (2) valid with restrictions
17-APR-2001 (8)

Value: 498 mg/L at 30 degree C
Qualitative: moderately soluble (>100-1000 mg/L)
Method: other: Handbook value
Testsubstance: other TS: m-nitrotoluene; purity not noted
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (2)

Value: 419 mg/L at 20 degree C
Qualitative: moderately soluble (>100-1000 mg/L)
Method: other
Testsubstance: other TS: m-nitrotoluene; purity not noted
Flag: Critical study for SIDS endpoint
17-APR-2001 (6)

2.6.2 Surface Tension

-

2.7 Flash Point

Value: 98 degree C
Type:
Method: other: DIN 51758
Year:
17-APR-2001 (3)

Value: 108 degree C
Type:
Method:
Year:
Source: Bayer AG Leverkusen
07-MAR-1994 (10)

Date: 17-APR-2001

2. Physico-chemical Data

ID: 99-08-1

2.8 Auto Flammability

Value:

Method: other: DIN 51794

Remark: Ignition temperature: ca. 450 degrees C

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(3)

2.9 Flammability

-

2.10 Explosive Properties

-

2.11 Oxidizing Properties

-

2.12 Additional Remarks

Remark: For further information see BUA report No. 41

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3. Environmental Fate and Pathways

Date: 17-APR-2001
ID: 99-08-1

3.1.1 Photodegradation

Type: water
Light source: Sun light
Light spect.: 313 - 366 nm
Conc. of subst.: .00001 mol/l at 4 degree C
DIRECT PHOTOLYSIS
Half-life t_{1/2}: 2.6 hour(s)
Quantum yield: .02
Method: other (measured)
Year: GLP: no data
Test substance: other TS: m-nitrotoluene; purity not noted
Method: Saturated solutions in distilled water were centrifuged at 15,000 rpm for 30 min. The supernatant was removed and diluted to concs of 10⁻⁶ to 10⁻⁵ M in distilled water, natural waters and aqueous solutions of extracted natural humic materials. Triplicate solutions were exposed to mid-day sunlight and monochromatic light (313 and 366 nm). The pH was 5.5. Exposure times were varied, achieving approx. 30% reaction for each exposure. Dark controls were used in each run. The solutions were then analyzed by reverse phase HPLC. Dark controls showed no transformation during the periods required for the experiments, which in most cases were less than 1 day.
Test substance: m-Nitrotoluene (99-08-1), purity: not given. Sample was purchased from Aldrich.
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (11)

Type: air
INDIRECT PHOTOLYSIS
Sensitizer: OH
Conc. of sens.: 1560000 molecule/cm³
Rate constant: .0000000000005808 cm³/(molecule * sec)
Degradation: 50 % after 18.4 day
Method: other (calculated): AOP Program v1.89
Year: 1999 GLP:
Test substance: other TS: molecular structure
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (8)

Date: 17-APR-2001
ID: 99-08-1

3. Environmental Fate and Pathways

3.1.2 Stability in Water

Type: abiotic
Degradation: 18 % after 8 day
at pH 7.4 and 25 degree C
Method: other: Canton, J.H. and Slooff, W. Ecotoxicol. Environ. Safety
6, 113-128 (1982).
Year: 1982 GLP: no data
Test substance: other TS: m-nitrotoluene; purity > 99.5%
Remark: Stability was determined in nonaerated standardized medium
before biodegradation studies.
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (12)

3.1.3 Stability in Soil

-

3.2 Monitoring Data (Environment)

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3.3.1 Transport between Environmental Compartments

Type: fugacity model level III
Media: other: air - biota - sediment(s) - soil - water
Air (Level I):
Water (Level I):
Soil (Level I):
Biota (L.II/III):
Soil (L.II/III):
Method: other: EPIWIN Fugacity model level III
Year: 1999
Result: Distribution Half-Life Emissions
Fugacity
(percent) (hr) (kg/hr) (atm)
Air 5.84 270 1000 1.77e-010
Water 30.4 900 1000 9.02e-010
Soil 63.5 900 1000 6.08e-009
Sediment 0.201 3.60e+003 0 7.88e-010
Persistence Time: 568 hr
Reaction Time: 1.14e+003 hr
Advection Time: 1.13e+003 hr
Percent Reacted: 49.6
Percent Advected: 50.4
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (8)

3.3.2 Distribution

3.4 Mode of Degradation in Actual Use

3.5 Biodegradation

Type: aerobic

Inoculum:

Concentration: 25 mg/l related to DOC (Dissolved Organic Carbon)

Contact time: 28 day

Degradation: 93 % after 28 day

Result: inherently biodegradable

14 day 75 %

28 day 93 %

Test substance: other TS: m-nitrotoluene; purity not noted

Method: Pitter, P. Water Res. 10, 231-235 (1976), modified. Two steps: acclimation of a mixed microbial population to the test substance in a semi-continuous activated sludge system and a die-away test in closed flasks. The main difference from Pitter's method is that the initial composition of the sludge, at the beginning of the acclimation-adaptation period, consists of a 1:1 (v/v) mixture of activated sludge from a domestic sewage plant and a solution containing organic material extracted from river mud.

Year: 1976 GLP: no data

Result: With inoculum concentration of 10 mg/l of dry matter, degradation after 2 weeks, 75%; after 4 weeks, 93%. A 10-fold higher concentration of adapted sludge resulted in 100% oxidation in 1 week. Adaptation failed when activated sludge from a domestic sewage plant was used exclusively. Under these conditions, no biodegradation occurred in 4 weeks.

Reliability: (2) valid with restrictions

Flag: Critical study for SIDS endpoint

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3. Environmental Fate and Pathways

Type: aerobic
Inoculum: other: sludge samplings from different sewage plants, rivers, bays and a lake
Concentration: 100 mg/l related to Test substance
Degradation: 2 % after 14 day
Method: OECD Guide-line 301 C "Ready Biodegradability: Modified MITI Test (I)" "Biodegradation test of chemical substance by microorganisms etc." stipulated in the Order Prescribing the Items of the Test Relating to the New Chemical Substance (1974, Order of the Prime Minister, Minister of Health and Welfare, the MITI No. 1). This guideline corresponds to "301C, Ready Biodegradability: Modified MITI Test I" stipulated in the OECD Guidelines for Testing of Chemicals (May 12, 1981).
Year: 1974 GLP: no data
Test substance: other TS: m-nitrotoluene; purity not noted
Remark: Sludge conc.: 30 mg/l
Reliability: (1) valid without restriction
Flag: Critical study for SIDS endpoint
17-APR-2001 (14)

Type: aerobic
Inoculum: predominantly domestic sewage, adapted
Degradation: 0 % after 20 day
Method: OECD Guide-line 301 D "Ready Biodegradability: Closed Bottle Test"
Year: 1977 GLP: no
Test substance:
Remark: Test conc.: 8, 24, 80 mg/l related to Test substance
17-APR-2001 (9)

Type: aerobic
Inoculum: activated sludge, adapted
Concentration: 200 mg/l related to COD (Chemical Oxygen Demand)
Degradation: 98.5 % after 5 day
Method: other: similar to Zahn-Wellens-Test
Year: GLP: no
Test substance: other TS: m-nitrotoluene; purity not noted
17-APR-2001 (9)

Type: aerobic
Inoculum: activated sludge, adapted
Degradation: < 10 % after 1 month
Result: other: not readily biodegradable
Test substance: other TS: m-nitrotoluene; purity > 99.5%
Method: Blok, J. Int. Biodeterior. Bull. 15, 57-63 (1979). OECD Determination of the Biodegradability of Anionic Surface Active Agents, OECD, Paris (1971). Pitter, P. Water Res. 10, 231-235 (1976).
Year: 1979 GLP:
17-APR-2001 (15)

3. Environmental Fate and Pathways

Date: 17-APR-2001

ID: 99-08-1

Type: aerobic
Inoculum: activated sludge, adapted
Concentration: 200 mg/l related to COD (Chemical Oxygen Demand)
Degradation: 98.5 % after 120 hour(s)
Method:
Year: GLP:
Test substance: other TS: m-nitrotoluene; purity not noted
Remark: Activated sludge was adapted for 20 days; Concentration of the inoculum was 100 mg/l; Average temperature during experiment = 20 degree C; Rate of biodegradation 21.0 mg COD/g.h

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3.6 BOD5, COD or BOD5/COD Ratio

3.7 Bioaccumulation

Species: Cyprinus carpio (Fish, fresh water)
Exposure period:
Concentration:
BCF:
Elimination:
Method:
Year: GLP:
Test substance:
Remark: Conc. ug/l BCF
25 0.47 - 8.5
2.5 3 - 12
log Pow : 2.4
% lipid, average 3.5
Methode: "Bioaccumulation test of chemical substance in fish and shellfish" stipulated in the Order Prescribing the Items of the Test Relating to the New Chemical Substance (1974, Order of the Prime Minister, the Minister of Health and Welfare, the MITI No. 1). This guideline corresponds to "305C, Bio- accumulation: Degree of Bioconcentration in Fish" stipulated in the OECD Guidelines for Testing of Chemicals (May 12, 1981).

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(14)

Species: Poecilia reticulata (Fish, fresh water)
Exposure period:
Concentration:
BCF:
Elimination:
Method:
Year: GLP:
Test substance:
Remark: BCF 56 (theoretical value)
BCF 16 (experimentally determined)

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(9)

3.8 Additional Remarks

-

AQUATIC ORGANISMS

4.1 Acute/Prolonged Toxicity to Fish

Type: flow through
Species: Pimephales promelas (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l Analytical monitoring: yes
LC50: 25.6
Method: other: The study was conducted according to ASTM E 729-80, Standard Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians, 1980.
Year: 1980 GLP: no data
Test substance: other TS: m-nitrotoluene purchased from Aldrich Chemical Company, Milwaukee, WI; purity = 99%
Remark: pH was adjusted to approximate that of Lake Superior water (pH 7.8) with NaOH or HCL. Compound analyses were done by GLC: all exposure chambers at 0,24,48,72, and 96 hr.
Fathead minnows used in this experiment were 33 days old and were cultured at US EPA Environmental Research Laboratory, Duluth, MN and University of Wisconsin - Superior campus.
25 fish/concentration and control. Behavior and toxic signs were noted at 4,24,48,72 and 96 hours. Affected fish lost schooling behavior, were hypoactive and lost equilibrium prior to death. Effect data were not recorded.
Test condition: temperature =25.3 degree C (+/-0.39);
dissolved oxygen = 7.6 mg/l; pH = 7.49;
hardness = 45.1 mg/l CaCO3; tank volume = 1 liter;
measured concentrations 4.44, 4.9, 7.1, 8.41, 10.5, 12.4, 17.5, 20.6, 30.7, 37.9 mg/l.
Reliability: (1) valid without restriction
Flag: Critical study for SIDS endpoint
17-APR-2001 (17)

Type: static
Species: Pimephales promelas (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l Analytical monitoring: no
LC50: 32.5
Method: other: The study was conducted according to ASTM E 729-80, Standard Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians, 1980.
Year: 1980 GLP: no
Test substance: other TS: m-nitrotoluene obtained from Pfaltz and Bauer; purity > 95%
Method: Method is described fully in the publication. Method follows ASTM E 729-80, Standard Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians, 1980.
Remark: Study reliability = 1 in AQUIRE
Reliability: (1) valid without restriction
Flag: Critical study for SIDS endpoint
17-APR-2001 (18)

Type: static
Species: Pimephales promelas (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l Analytical monitoring: no
LC50: 30
Method: GLP: no
Year: GLP: no
Test substance: other TS: m-Nitrotoluene (99-08-1) , obtained from Curtin Matheson Scientific, Inc; purity: reagent grade
Method: The Committee on Methods for Toxicity Tests with Aquatic Organisms. 1975. Methods for acute toxicity tests with fish, macroinvertebrates, and amphibians. U.S. Environmental Protection Agency, Duluth, Minn. Ecological Research Series EPA-660/3-75-009. 67 p.
Result: 1hr 24hr 48hr 72hr 96hr
LC50 43 30 30 30 30 (mg/l)
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (19)

Type: semistatic
Species: Poecilia reticulata (Fish, fresh water)
Exposure period: 14 day
Unit: mg/l Analytical monitoring:
Method: other: Koenemann, 1979 GLP:
Year: GLP:
Test substance: other TS: purity > 99.5 %
Remark: LC50: 37 mg/l (mortality)
EC50: 7.4 mg/l (behaviour)
nominal conc.
17-APR-2001 (9)

Type: static
Species: Pimephales promelas (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l Analytical monitoring: no
LC50: 19 - 50
Method: other: abstract only, method not given
Year: GLP:
Test substance: other TS: m-nitrotoluene; purity not noted
Remark: These data may be from the same study as Bailey, H.C., and Spanggord, R.J., (1983). Study reliability = 2 in AQUIRE
Reliability: (2) valid with restrictions
17-APR-2001 (20)

Type: static
Species: Leuciscus idus (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l Analytical monitoring: no
LC0: 56.2
Method:
Year: 1986 GLP: no
Test substance:
Remark: direct weight
17-APR-2001 (9)

Type: static
Species: Brachydanio rerio (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l Analytical monitoring: no
LC0: 42.2
LC100: 75
Method: other: Letale Wirkung beim Zebrabaerbling, UBA-Verfahrensvorschlag, Mai 1984, Letale Wirkung beim Zebrabaerbling Brachydanio rerio LC0, LC50, LC100, 48-96h
Year: 1986 GLP: no
Test substance:
Remark: direct weight
17-APR-2001 (9)

Type:
Species: other: Oryzias latipes (Reiskaerpfling)
Exposure period: 96 hour(s)
Unit: mg/l Analytical monitoring:
LC50: 30
Method: other: semi-static
Year: GLP:
Test substance:
17-APR-2001 (9)

Type:
Species: Brachydanio rerio (Fish, fresh water)
Exposure period: 14 day
Unit: mg/l Analytical monitoring: yes
NOEC: 1.26
Method: other: OECD 204: Fish, Prolonged Toxicity Test: 14-day Study
(4 April 1984)
Year: GLP:
Test substance:
Remark: analytic. conc.
17-APR-2001 (21)

Type:
Species: Brachydanio rerio (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l Analytical monitoring: yes
LC50: 33.14
Method: OECD Guide-line 203 "Fish, Acute Toxicity Test"
Year: GLP:
Test substance:
Remark: analyt. conc.
17-APR-2001 (21)

Type:
Species: other: Oryzias latipes (Reiskaerpfling)
Exposure period: 48 hour(s)
Unit: mg/l Analytical monitoring:
LC50: 71
Method: other: Japanese Industrial Standard (JIS K 0102-1986-71)
"Testing methods for industrial waste water"
Year: GLP: no data
Test substance:
Remark: Water solubility: 300 mg/l
17-APR-2001 (14)

4.2 Acute Toxicity to Aquatic Invertebrates

Type: static
Species: Daphnia magna (Crustacea)
Exposure period: 48 hour(s)
Unit: mg/l Analytical monitoring: no
LC50 : 7.5
Method: NEN 6501, Determination of acute toxicity with Daphnia magna. Dutch Standardization Organization, Rijswijk, the Netherlands (1980), with slight modifications according to Van Leeuwen, C.J. et al., Aquatic toxicological aspects of dithiocarbamates and related compounds. Short-term tests. Aquat. Toxicol. 7, 145-164 (1985).
Year: 1980 GLP: no
Test substance: other TS: m-nitrotoluene; purity > 98%
Reliability: (1) valid without restriction
Flag: Critical study for SIDS endpoint
17-APR-2001 (22)

Type: Daphnia magna (Crustacea)
Species: Daphnia magna (Crustacea)
Exposure period: 24 hour(s)
Unit: mg/l Analytical monitoring: no
LC50 : 35
Method: other: according to Bringmann, G. and Kuhn, R., (1977)
Year: GLP: no
Test substance: other TS: m-nitrotoluene; purity not noted
Remark: Study reliability = 1 in AQUIRE
Reliability: (1) valid without restriction
Flag: Critical study for SIDS endpoint
17-APR-2001 (23)

Type: Daphnia magna (Crustacea)
Species: Daphnia magna (Crustacea)
Exposure period: 48 hour(s)
Unit: mg/l Analytical monitoring: yes
EC50: 7.4
LC50 : 17.6
Method: other: OECD Proposal, 1979
Year: GLP: no
Test substance: other TS: m-nitrotoluene; purity > 95%
17-APR-2001 (9)

Type:
Species: Daphnia magna (Crustacea)
Exposure period: 24 hour(s)
Unit: mg/l Analytical monitoring:
EC50: 24
Method: other: Bringmann, G.; Kuehn, R.: Ergebnisse der Schadwirkung
wassergefaehrdender Stoffe gegen Daphnia magna in einem
weiterentwickelten standardisierten Testverfahren. Z. Wasser
Abwasser Forsch. 15 (1), 1-6 (1982)
Year: 1982 GLP: no
Test substance:
17-APR-2001 (9)

Type:
Species: Daphnia magna (Crustacea)
Exposure period: 48 hour(s)
Unit: mg/l Analytical monitoring:
LC50 : 28.1
Method:
Year: GLP:
Test substance:
17-APR-2001 (9)

4.3 Toxicity to Aquatic Plants e.g. Algae

Species: Chlorella pyrenoidosa (Algae)
Endpoint: growth rate
Exposure period: 96 hour(s)
Unit: mg/l Analytical monitoring: no
EC50: 14
Method: OECD, 1984. Guidelines for testing of chemicals.
Organisation for Economic Cooperation and Development,
Paris, Guideline 201, with slight modifications according
to Van Leeuwen, C.J. et al., Aquatic toxicological aspects
of dithiocarbamates and related compounds. Short-term tests.
Aquat. Toxicol. 7, 145-164 (1985).
Year: 1984 GLP: no
Test substance: other TS: m-nitrotoluene; purity > 98%
Remark: Study reliability = 2 in AQUIRE
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (22)

Species: Scenedesmus quadricauda (Algae)
 Endpoint: growth rate
 Exposure period: 7 day
 Unit: mg/l Analytical monitoring: no
 LOEC: 4.4
 Method: other: according to Bringmann and Kuhn (1980)
 Year: GLP: no
 Test substance: other TS: m-Nitrotoluene (99-08-1) , purity: not given
 Remark: Study reliability = 2 in AQUIRE
 Reliability: (2) valid with restrictions
 01-JUN-2000 (24)

Species: Chlorella pyrenoidosa (Algae)
 Endpoint: other: cell count
 Exposure period: 96 hour(s)
 Unit: mg/l Analytical monitoring:
 EC50: 14
 Method:
 Year: GLP:
 Test substance:
 17-APR-2001 (9)

Species: Scenedesmus quadricauda (Algae)
 Endpoint: other: cell count
 Exposure period: 8 day
 Unit: mg/l Analytical monitoring:
 TT : 4.4
 Method: other: see remarks
 Year: GLP: no
 Test substance:
 Remark: Grenzwerte der Schadwirkung wassergefahrender Stoffe gegen
 Bakterien (Pseudomonas putida) und Gruenlagen (Scenedesmus
 quadricauda) im Zellvermehrungshemmtest. Bringmann, G.;
 Kuehn, R.: Z. f. Wasser- und Abwasser-Forschung 10 (3/4),
 87-98 (1977)
 TT = Toxicity Threshold
 17-APR-2001 (9)

4.4 Toxicity to Microorganisms e.g. Bacteria

Type: aquatic
 Species: Photobacterium phosphoreum (Bacteria)
 Exposure period: 15 minute(s)
 Unit: mg/l Analytical monitoring: no
 EC50: 3.95
 Method:
 Year: GLP:
 Test substance:
 Remark: Microtox
 17-APR-2001 (9)

Type: aquatic
 Species: Pseudomonas putida (Bacteria)
 Exposure period: 16 hour(s)
 Unit: mg/l Analytical monitoring: no
 TT : 10
 Method: other: see remarks
 Year: GLP: no
 Test substance:
 Remark: Grenzwerte der Schadwirkung wasergefaehrender Stoffe gegen
 Bakterien (Pseudomonas putida) und Gruenlagen (Scenedesmus
 quadricauda) im Zellvermehrungshemmtest. Bringmann, G.;
 Kuehn, R.: Z. f. Wasser- und Abwasser-Forschung 10 (3/4),
 87-98 (1977)
 TT = Toxicity threshold

17-APR-2001 (9)

Type:
 Species: Tetrahymena pyriformis (Protozoa)
 Exposure period: 24 hour(s)
 Unit: mg/l Analytical monitoring:
 EC50: 50
 Method: other: cell multiplication inhibition test
 Year: GLP:
 Test substance:
 17-APR-2001 (9)

4.5 Chronic Toxicity to Aquatic Organisms

4.5.1 Chronic Toxicity to Fish

Species: Oryzias latipes (Fish, fresh water)
 Endpoint:
 Exposure period: 28 day
 Unit: mg/l Analytical monitoring:
 NOEC: 2
 EC50 : 3
 Method:
 Year: GLP:
 Test substance:
 Remark: LC50: 9.9 mg/l
 semi-static

17-APR-2001 (9)

4.5.2 Chronic Toxicity to Aquatic Invertebrates

Species: Daphnia magna (Crustacea)
Endpoint:
Exposure period: 21 day
Unit: mg/l Analytical monitoring: no
NOEC: 1.8
Method: other: according to Bringmann, G. and Kuhn, R., (1977)
Year: GLP: no data
Test substance:

Study reliability = 1 in AQUIRE

21-AUG-2000

(25)

Species: Daphnia magna (Crustacea)
Endpoint:
Exposure period: 21 day
Unit: mg/l Analytical monitoring:
Method:
Year: GLP:
Test substance:
Remark: LC50: 9 mg/l
EC50 (mortality and immobilization): 9 mg/l
EC50 (effect on reproduction): 3.5 mg/l
NOEC (reproduction): 0.5 mg/l

17-APR-2001

(9)

TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Soil Dwelling Organisms

-

4.6.2 Toxicity to Terrestrial Plants

-

4.6.3 Toxicity to other Non-Mamm. Terrestrial Species

-

4.7 Biological Effects Monitoring

-

4.8 Biotransformation and Kinetics

-

4.9 Additional Remarks

Remark: See BUA Report 41 for further ecotoxicological data.
17-APR-2001

5.1 Acute Toxicity

5.1.1 Acute Oral Toxicity

Type: LD50
Species: rat
Strain: Wistar
Sex: male/female
Number of Animals: 10
Vehicle: other: olive oil
Value: 2000 - 2200 mg/kg bw
Method: Miller, L.C. and Tainter, M.L., Proc. Soc. Exp. Biol. Med. 57, 261-264 (1944); Bartlett, M.S., Suppl. I. Roy.Stat. 4, 137-170 (1937).
Year: 1937, 1944 GLP: no data
Test substance: other TS: m-nitrotoluene; purity = 99%
Method:
Remark: Volume given was 1 ml per 200 g/b.w.
Result: 2200 (+/-145) mg/kg b.w. for males;
2000 (+/-145) mg/kg b.w. for females
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (26) (27)

Type: LD50
Species: rat
Strain: Sprague-Dawley
Sex: male
Number of Animals: 5
Vehicle: other: olive oil
Value: = 1070 mg/kg bw
Method: other: Smyth, H.F. Jr., Amer. Ind. Hyg. Ass. J. 23, 95-107 (1962);
Thompson, W.R., Bact. Rev. 11, 115-145 (1947); Weil, C.S., Biometrics 8, 249-263 (1952); Finney, D.J., Probit Analysis. Cambridge University Press, London. (1971).
Year: 1947, 1962, 1971 GLP: no data
Test substance: other TS: m-Nitrotoluene (99-08-1), purity: not given
17-APR-2001 (28)

Type: LD50
Species: rat
Strain:
Sex: male
Number of Animals: 5
Vehicle:
Value: ca. 2121 mg/kg bw
Method:
Year: GLP:
Test substance:
17-APR-2001 (29)

Type: LD50
Species: rat
Strain:
Sex:
Number of
Animals:
Vehicle:
Value: ca. 1784 mg/kg bw
Method:
Year: GLP:
Test substance:
Remark: sex: female
17-APR-2001 (29)

Type: LD50
Species: rat
Strain:
Sex:
Number of
Animals:
Vehicle:
Value: = 1072 mg/kg bw
Method:
Year: GLP:
Test substance:
17-APR-2001 (30)

Type: LD50
Species: mouse
Strain: other: CF1
Sex:
Number of
Animals:
Vehicle:
Value: 1230 mg/kg bw
Method: Smyth, H.F. Jr., Amer. Ind. Hyg. Ass. J. 23, 95-107 (1962);
Thompson, W.R., Bact. Rev. 11, 115-145 (1947); Weil, C.S.,
Biometrics 8, 249-263 (1952); Finney, D.J., Probit Analysis.
Cambridge University Press, London. (1971).
Year: 1947, 1962, 1971 GLP: no data
Test substance: other TS: m-Nitrotoluene (99-08-1), purity: not given
Remark: Vehicle and dose volume not given
17-APR-2001 (28)

Type: LD50
Species: mouse
Strain:
Sex:
Number of
Animals:
Vehicle:
Value: = 1231 mg/kg bw
Method:
Year: GLP:
Test substance:
17-APR-2001 (30)

5.1.2 Acute Inhalation Toxicity

Type: LC50
Species: rat
Strain: Sprague-Dawley
Sex: male
Number of
Animals: 10
Vehicle: none
Exposure time: 4 hour(s)
Value: > 157 ppm
Method: Finney, D.J., Probit Analysis, 2nd ed, King Review Press
(1952).
Year: GLP:
Test substance:
Remark: There were no deaths during exposure or during the 14 day
observation period. All animals gained weight; there were
no gross lesions attributed to exposure. 157 ppm was 77% of
saturation.
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (31)

Type: LC50
Species: mouse
Strain: other: CF1
Sex: male
Number of
Animals: 10
Vehicle: none
Exposure time: 4 hour(s)
Value: > 151 ppm
Method: Finney, D.J., Probit Analysis, 2nd ed, King Review Press
(1952).
Year: GLP:
Test substance:
Remark: There were no deaths during exposure or during the 14 day
observation period. All animals gained weight; there were
no gross lesions attributed to exposure. 151 ppm was 74% of
saturation.

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5. Toxicity

saturation.

Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (31)

Type: LC50
Species: rat
Strain:
Sex:
Number of
Animals:
Vehicle:
Exposure time: 1 hour(s)
Value: > 2.417 mg/l
Method:
Year: GLP:
Test substance:
Remark: mortality: 0/5
17-APR-2001 (29)

Type: LC50
Species: mouse
Strain:
Sex:
Number of
Animals:
Vehicle:
Exposure time: 1 hour(s)
Value: > 2.417 mg/l
Method:
Year: GLP:
Test substance:
Remark: mortality: 0/10
17-APR-2001 (29)

5.1.3 Acute Dermal Toxicity

Type: LD50
Species: rabbit
Strain: New Zealand white
Sex: female
Number of
Animals: 3
Vehicle: none
Value: > 20000 mg/kg bw
Method:
Year: GLP: no data
Test substance: other TS: m-Nitrotoluene (99-08-1) , purity not noted
Remark: Doses were kept in contact with the skin for 24 hours and
the rabbits then observed for 14 days. No observable toxic
effects were seen. All rabbits gained weight normally during
the 14 day observation period.
Reliability: (2) valid with restrictions

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5. Toxicity

Flag: Critical study for SIDS endpoint
17-APR-2001 (31)

Type: LD50
Species: rat
Strain:
Sex:
Number of
Animals:
Vehicle:
Value: > 1157 mg/kg bw
Method:
Year: GLP:
Test substance:
Remark: LD50 > 1.0 ml/kg, mortality: 0/10
17-APR-2001 (29)

5.1.4 Acute Toxicity, other Routes

Type: LD50
Species: rat
Strain:
Sex:
Number of
Animals:
Vehicle:
Route of admin.: other: no data
Value: = 2400 mg/kg bw
Method:
Year: GLP:
Test substance:
17-APR-2001 (32)

Type: LD50
Species: rat
Strain:
Sex:
Number of
Animals:
Vehicle:
Route of admin.: other: no data
Value: = 1590 mg/kg bw
Method:
Year: GLP:
Test substance:
17-APR-2001 (33)

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Date: 17-APR-2001
ID: 99-08-1

5. Toxicity

Type: LD50
Species: mouse

Strain:
Sex:
Number of
Animals:
Vehicle:
Route of admin.: other: no data
Value: = 330 mg/kg bw
Method:
Year: GLP:
Test substance:
17-APR-2001 (32)

Type: LD50
Species: mouse
Strain:
Sex:
Number of
Animals:
Vehicle:
Route of admin.: other: no data
Value: = 800 mg/kg bw
Method:
Year: GLP:
Test substance:
17-APR-2001 (33)

Type: LD50
Species: rabbit
Strain:
Sex:
Number of
Animals:
Vehicle:
Route of admin.: other: no data
Value: = 1750 mg/kg bw
Method:
Year: GLP:
Test substance:
17-APR-2001 (33)

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Date: 17-APR-2001
ID: 99-08-1

5. Toxicity

Type: LD50
Species: rabbit

Strain:
Sex:
Number of
Animals:
Vehicle:
Route of admin.: other: no data
Value: = 2400 mg/kg bw
Method:
Year: GLP:
Test substance:
17-APR-2001 (32)

Type: LD50
Species: guinea pig
Strain:
Sex:
Number of
Animals:
Vehicle:
Route of admin.: other: no data
Value: = 3600 mg/kg bw
Method:
Year: GLP:
Test substance:
17-APR-2001 (32)

5.2 Corrosiveness and Irritation

5.2.1 Skin Irritation

Species: rabbit
Concentration: undiluted

Exposure: 580 mg/rabbit
Exposure Time: 24 h
Number of
Animals: 6
PII: 0.37/8.0
Result: slightly irritating
EC classificat.: non irritant
Method: Journal Officiel de la Republique Francaise, Avril 1971, no. 7
156.
Year: 1971 GLP:
Test substance: m-nitrotoluene, 99% purity
Remark: applied to intact and abraded areas of the back
17-APR-2001 (34) (27)

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5. Toxicity

Date: 17-APR-2001
ID: 99-08-1

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of
Animals:
PDII:
Result: not irritating
EC classificat.:
Method: other
Year: GLP:
Test substance:
17-APR-2001 (29)

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of
Animals:
PDII:
Result: not irritating
EC classificat.:
Method: other: according to Draize
Year: GLP:
Test substance:
17-APR-2001 (35)

5.2.2 Eye Irritation

Species: rabbit
Concentration: neat
Dose: 0.1 ml/rabbit
Exposure Time: 72 h
Comment:
Number of
Animals: 6
Result: 0/110, not irritating
EC classificat.: non irritant
Method: Journal Officiel de la Republique Francaise, Avril 1971, no. 7
156.
Year: 1971 GLP:
Test substance: m-nitrotoluene, 99%
Remark: time of reading: 24, 48, 72 h
17-APR-2001 (34) (27)

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Date: 17-APR-2001
ID: 99-08-1

5. Toxicity

Species: rabbit

Concentration:
 Dose:
 Exposure Time:
 Comment:
 Number of
 Animals:
 Result: slightly irritating
 EC classificat.:
 Method: other
 Year: GLP:
 Test substance:
 17-APR-2001 (29)

5.3 Sensitization

-

5.4 Repeated Dose Toxicity

Species: rat Sex: male/female
 Strain: other: F344/N
 Route of admin.: oral feed
 Exposure period: 13 w
 Frequency of
 treatment: daily
 Post. obs.
 period: no
 Doses: 625,1250,2500,5000,10000 ppm (=ca. 47,94,188,375,750 mg/kg bw)
 Control Group: yes, concurrent no treatment
 LOAEL: 625 ppm
 Method: other: NTP Program
 Year: GLP: yes
 Test substance: other TS: m-nitrotoluene; purity >96%
 Remark: 10 rats/sex/group
 Result: No effect on survival; decreased wt gain and increased
 relative liver wt (M+F) at 10000 ppm; increased bile acids
 in M's at 5000 and 10000 ppm and in F's at 10000 ppm; mild
 increase in ALT in F's at 2500, 5000 and 10000 ppm;
 increased relative kidney wt at 10000 ppm (M's) and 5000 ppm
 (F's); hyaline droplet nephropathy in M's at all dose
 levels; changes in hematology and clinical chemistry in both
 sexes at all doses, including increased methemoglobin at
 10000 (M+F) and at 5000 (M's); hemosiderin and/or congestion
 in the spleen in both sexes at 5000 and 10000 ppm.
 Testicular degeneration occurred in all M's at 10000 ppm,
 along with decreased epididymal sperm count and
 concentration. The length of the estrous cycle increased at
 5000 and 10000 ppm, while the number of cycling animals
 decreased.
 Reliability: (1) valid without restriction
 Flag: Critical study for SIDS endpoint
 17-APR-2001 (36) (37)

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5. Toxicity

Date: 17-APR-2001
 ID: 99-08-1

Species: mouse Sex: male/female

Strain: B6C3F1
 Route of admin.: oral feed
 Exposure period: 13 w
 Frequency of treatment: daily
 Post. obs. period: no
 Doses: 625,1250,2500,5000,10000 ppm (=ca. 101,187,375,750,1500 mg/kg bw)
 Control Group: yes, concurrent no treatment
 LOAEL: 625 - 675 ppm
 Method: other: NTP Program
 Year: GLP: yes
 Test substance: other TS: m-nitrotoluene; purity >96%
 Remark: 10 animals/sex/group
 Result: No effect on survival; decreased food consumption, decreased wt gain in both sexes at 5000 and 10000 ppm; increased relative liver wts in both sexes at all doses, no gross or microscopic liver lesions; increased relative lung wts in both sexes at 10000 ppm; no toxicity to reproduction system.
 Reliability: (1) valid without restriction
 Flag: Critical study for SIDS endpoint
 17-APR-2001 (36) (37)

Species: rat Sex: male/female
 Strain: Wistar
 Route of admin.: gavage
 Exposure period: 4 w
 Frequency of treatment: once/d, 5 d/w
 Post. obs. period: no data
 Doses: 500, 1000 mg/kg bw in olive oil
 Control Group: yes, concurrent vehicle
 Method:
 Year: GLP:
 Test substance:
 Result: 500 mg-group: disorder of breathing, weariness and behavior disorder; 1000 mg-group: additionally: elevation of respiratory rate, convulsion, atonia, loss of weight; mortality: 12/20
 17-APR-2001 (26) (27)

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Date: 17-APR-2001
 ID: 99-08-1

5. Toxicity

Species: rat Sex: male/female

Strain: Wistar
Route of admin.: gavage
Exposure period: 24 w
Frequency of treatment: once/d, 5 d/w
Post. obs. period: no
Doses: 300 mg/kg bw in olive oil
Control Group: yes, concurrent vehicle
Method:
Year: GLP:
Test substance:
Result: no signs of intoxication, number of erythrocytes and leucocytes not altered, decrease in hemoglobin content for about 10 %; females only: loss of hair

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(38) (27)

Species: rat Sex: no data
Strain: no data
Route of admin.: oral unspecified
Exposure period: 4-12 w (1-3 months)
Frequency of treatment: not mentioned
Post. obs. period: no data
Doses: 0.1-0.2 LD50 for rats
Control Group: other: keine Angabe
Method:
Year: GLP:
Test substance:
Result: anemia accompanied by reticulocytosis and a decrease in the level of SH-groups and an increase in that of fibrinogen in the blood.

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(39)

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Date: 17-APR-2001
ID: 99-08-1

5. Toxicity

Species: rat Sex: no data

Strain: no data
 Route of admin.: oral feed
 Exposure period: no data
 Frequency of treatment: daily
 Post. obs. period: no data
 Doses: 240, 480 mg/kg (1/10, 1/5 LD50)
 Control Group: yes
 Method:
 Year: GLP:
 Test substance:
 Result: decreased hemoglobin content and erythrocyte count, increased number of leucocytes and increased methemoglobin level, impairment of the antitoxic function of the liver measured by the increase in urinary hippuric acid, shortened thromboplastin time and raised prothrombin index
 17-APR-2001 (40)

Species: rat Sex: male/female
 Strain: other: F344/N
 Route of admin.: oral feed
 Exposure period: 14 d
 Frequency of treatment: daily
 Post. obs. period: no
 Doses: 625, 1250, 2500, 5000, 10000 ppm (=ca. 47, 94, 188, 375, 750 mg/kg bw)
 Control Group: yes
 Method:
 Year: GLP:
 Test substance:
 Remark: dose finding study for the 13 week toxicity study
 5 rats/sex/group
 Result: no effect on survival; 5000 ppm (m), 10000 ppm (m,f): reduced weight gain and reduced food consumption; no other signs of toxicity
 17-APR-2001 (36) (37)

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Date: 17-APR-2001
 ID: 99-08-1

5. Toxicity

Species: mouse Sex: male/female

Strain: B6C3F1
Route of admin.: oral feed
Exposure period: 14 d
Frequency of treatment: daily
Post. obs. period: no
Doses: 388,675,1250,2500,5000 ppm (=ca. 58,101,187,375,750 mg/kg bw)
Control Group: yes
Method:
Year: GLP:
Test substance: as prescribed by 1.1 - 1.4
Remark: dose finding study for the 13 week toxicity study
5 rats/sex/group
Result: no effects on survival, no clinical signs of toxicity
17-APR-2001 (36) (37)

Species: mouse Sex: female
Strain: B6C3F1
Route of admin.: gavage
Exposure period: 14 d
Frequency of treatment: daily
Post. obs. period: no data
Doses: 200, 400, 600 mg/kg
Control Group: other: keine Angabe
Method:
Year: GLP:
Test substance:
Result: Suppression of IgM antibody forming cell response to the
T-dependent antigen from sheep erythrocytes (no further
information), in a dose dependent manner; max. suppression:
38 %
17-APR-2001 (41)

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5. Toxicity

Date: 17-APR-2001
ID: 99-08-1

Species: mouse

Sex: female

Strain: B6C3F1
 Route of admin.: gavage
 Exposure period: 14 d
 Frequency of treatment: daily
 Post. obs. period: no
 Doses: 200, 400, 600 mg/kg bw in corn oil
 Control Group: yes, concurrent vehicle
 Method: other
 Year: 1992 GLP: no data
 Test substance: other TS: purity: 99 %
 Result: The present analyses indicated that the performance of only two or three immunotoxic tests are sufficient to predict immunotoxic compounds in rodents: the tests that showed the highest association with immunotoxicity were the splenic antibody plaque forming cell response and the cell surface marker analysis. m-Nitrotoluene was judged to be immunotoxic. The analyses suggested that potential immunotoxic compounds are likely to be rodent carcinogens but there was no relationship between immunotoxicity and mutagenicity.

17-APR-2001 (42) (43)

Species: mouse Sex: no data
 Strain: no data
 Route of admin.: other
 Exposure period: 20 d
 Frequency of treatment: daily
 Post. obs. period: no data
 Doses: 1/5 LD50
 Control Group: other: keine Angabe
 Method:
 Year: GLP:
 Test substance:
 Result: no cumulative effect observed

17-APR-2001 (32)

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Date: 17-APR-2001
ID: 99-08-1

5. Toxicity

5.5 Genetic Toxicity 'in Vitro'

Type: Ames test
System of testing: Salmonella typhimurium TA98, TA100, TA1535, TA1537
Concentration: 0, 3.3, 10, 33, 100, 333ug/plate
Cytotoxic Conc.: with and without metabolic activation: 333.0 ug/plate
Metabolic activation: with and without
Result: negative
Method: Yahagi, T. et al, Cancer Lett 1, 91-96 (1975); Ames, B.N. et al, Mutat. Res. 31, 347-364 (1975).
Year: 1975 GLP: no data
Test substance: as prescribed by 1.1 - 1.4
Remark: Both male Sprague-Dawley rat liver and male Syrian hamster liver used for metabolic activation. DMSO used as a solvent. Preincubation protocol used. Positive response was a reproducible, dose-related increase whether 2X background or not.
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (36) (44) (45)

Type: Cytogenetics assay
System of testing: Chinese Hamster ovary (CHO) cells
Concentration: 150, 300, 398, 437, 460, 483 ug/ml
Cytotoxic Conc.: see remarks below
Metabolic activation: with and without
Result: negative
Method: other: Galloway, S.M. et al., Environ. Mutagen. 7(1) 1-51 (1985)
Year: 1985 GLP: no data
Test substance: m-nitrotoluene, purity not given
Remark: The top dose selected was estimated to reduce growth by 50%; cell growth and cell cycle kinetics information from the SCE test were also used to select doses.
Author's remarks: The aberration tests with and without S9 were negative whether cells were fixed at 11 hr or at 20 hr.
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (36) (46) (47)

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5. Toxicity

Date: 17-APR-2001
ID: 99-08-1

Type: Sister chromatid exchange assay
System of testing: Chinese Hamster ovary (CHO) cells

Concentration: 150, 248, 299, 300, 345, 398 ug/ml without activation;
 Cytotoxic Conc.: see remarks below
 Metabolic
 activation: with and without
 Result: positive without activation
 Method: other: Galloway, S.M. et al., Environ. Mutagen. 7(1) 1-51 (1985)
 Year: 1985 GLP: no data
 Test substance: other TS: m-nitrotoluene (99-08-1), purity: not given

 Remark: Author's remarks: In the first SCE test, cells were exposed to a range of doses from 4 to 5 orders of magnitude, up to a maximum dose of 5-10 mg/ml or to the limits of solubility in culture medium. Dose selection for repeat trials involved a range of doses based on observations from the first trial. SCE's were induced only without metabolic activation and only in the presence of severe cell cycle delay.
 Reliability: (2) valid with restrictions
 17-APR-2001 (36) (46) (47)

Type: Ames test
 System of
 testing: Salmonella typhimurium TA98, TA100
 Concentration:
 Cytotoxic Conc.:
 Metabolic
 activation: with and without
 Result: negative
 Method:
 Year: GLP:
 Test substance:
 17-APR-2001 (48)

Type: Ames test
 System of
 testing: Salmonella typhimurium TA98, TA100
 Concentration:
 Cytotoxic Conc.:
 Metabolic
 activation: with and without
 Result: negative
 Method:
 Year: GLP:
 Test substance:
 17-APR-2001 (49)

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Date: 17-APR-2001
ID: 99-08-1

5. Toxicity

Type: Ames test
 System of
 testing: Salmonella typhimurium TA98, TA100, TA1535, TA1537, TA1538
 Concentration:

Cytotoxic Conc.:
Metabolic
activation: with and without
Result: negative
Method:
Year: GLP:
Test substance:
17-APR-2001 (50)

Type: Ames test
System of
testing: Salmonella typhimurium TA98, TA100, TA1535, TA1537, TA1538
Concentration:
Cytotoxic Conc.:
Metabolic
activation: with and without
Result: negative
Method:
Year: GLP:
Test substance:
17-APR-2001 (51) (52)

Type: Ames test
System of
testing: Salmonella typhimurium TA98, TA100
Concentration:
Cytotoxic Conc.:
Metabolic
activation: with and without
Result: negative
Method:
Year: GLP:
Test substance:
Remark: TA98 strains with added norharman
17-APR-2001 (53)

Type: Ames test
System of
testing: Salmonella typhimurium TA98, TA100
Concentration:
Cytotoxic Conc.:
Metabolic
activation: with and without
Result: negative
Method:
Year: GLP:
Test substance:
17-APR-2001 (54)

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Date: 17-APR-2001
ID: 99-08-1

5. Toxicity

Type: Ames test
System of
testing: Salmonella typhimurium TA92, TA94, TA98, TA100, TA1535, TA1537
Concentration:

Cytotoxic Conc.:
Metabolic
activation: with and without
Result: negative
Method:
Year: GLP:
Test substance:
17-APR-2001 (55)

Type: Bacillus subtilis recombination assay
System of
testing: bacillus subtilis H17, M45
Concentration:
Cytotoxic Conc.:
Metabolic
activation: without
Result: negative
Method:
Year: GLP:
Test substance:
17-APR-2001 (50)

Type: Cytogenetics assay
System of
testing: human peripheral lymphocytes
Concentration: 0, 0.002, 0.020, 0.10, 0.50 mmol/l
Cytotoxic Conc.:
Metabolic
activation: without
Result: positive
Method: other: incubation 24 hrs after treatment, chromosome
preparations
Year: 1995 GLP: no data
Test substance: no data
17-APR-2001 (56) (57)

Type: Cytogenetics assay
System of
testing: Chinese Hamster ovary cells (CHO)
Concentration:
Cytotoxic Conc.:
Metabolic
activation: with and without
Result: negative
Method:
Year: GLP:
Test substance:
17-APR-2001 (36) (46) (47)

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Date: 17-APR-2001
ID: 99-08-1

5. Toxicity

Type: Unscheduled DNA synthesis
System of
testing: rat hepatocytes
Concentration: 0, 0.1, 0.5, 1, 5, 10, 50, 100 ug/ml 1 % DMSO

Cytotoxic Conc.:
Metabolic
activation: no data
Result: negative
Method: other: test substance dissolved in DMSO, DMSO control,
hepatocytes cultured in serum free defined media (WEM)
1995 GLP: no data
Year:
Test substance: other TS: purity: 98 %
17-APR-2001 (58)

Type: Unscheduled DNA synthesis
System of
testing: rat spermatocytes, rat spermatids
Concentration:
Cytotoxic Conc.:
Metabolic
activation: without
Result: negative
Method:
Year: GLP:
Test substance:
17-APR-2001 (59)

Type: Unscheduled DNA synthesis
System of
testing: rat hepatocytes
Concentration:
Cytotoxic Conc.:
Metabolic
activation: without
Result: negative
Method:
Year: GLP:
Test substance:
17-APR-2001 (60)

Type: other: Chromosome Aberration Assay
System of
testing: Chinese Hamster lung (CHL) cells
Concentration:
Cytotoxic Conc.:
Metabolic
activation: without
Result: negative
Method:
Year: GLP:
Test substance:
Remark: significant increase of polyploid cells
17-APR-2001 (61)

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Date: 17-APR-2001
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5. Toxicity

5.6 Genetic Toxicity 'in Vivo'

Type: Unscheduled DNA synthesis
Species: other: rat hepatocytes Sex: male

Strain: Fischer 344
Route of admin.: gavage
Exposure period: once
Doses: 100-750 mg/kg bw
Result: negative
Method: other: 12 week old rats, UDS measured in primary cultures of hepatocytes derived from rats 12 hrs after treatment
Year: 1991 GLP: no data
Test substance: other TS: m-nitrotoluene; purity not noted
Result: 3-Nitrotoluene did not induce UDS
17-APR-2001 (62)

Type: other: induction of scheduled DNA synthesis (S-Phase)
Species: other: rat hepatocytes Sex: male
Strain: Fischer 344
Route of admin.: gavage
Exposure period: once
Doses: 100-750 mg/kg bw
Result:
Method: other: 12 week old rats, S-phase was measured in primary hepatocytes 24 and 48 hrs after treatment
Year: 1991 GLP: no data
Test substance: other TS: m-nitrotoluene; purity not noted
Result: 3-Nitrotoluene induced S-phase activity 48 hrs after doing
17-APR-2001 (62)

Type: Unscheduled DNA synthesis
Species: other: rat hepatocytes Sex: male
Strain:
Route of admin.: oral unspecified
Exposure period: once
Doses: 100, 500 mg/kg
Result: negative
Method:
Year: GLP:
Test substance:
Result: no induction of UDS
17-APR-2001 (63)

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5. Toxicity

Date: 17-APR-2001
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Type: Unscheduled DNA synthesis
Species: other: rat hepatocytes Sex: male
Strain:
Route of admin.: gavage

Exposure period: once
Doses: 200,500 mg/kg bw in corn oil
Result: negative
Method:
Year: GLP:
Test substance:
Result: no induction of UDS
17-APR-2001 (64) (60) (65)

Type: Unscheduled DNA synthesis
Species: other: rat hepatocytes Sex: no data
Strain:
Route of admin.: oral unspecified
Exposure period: no information
Doses: 200 mg/kg
Result: negative
Method:
Year: GLP:
Test substance:
Result: no induction of UDS
17-APR-2001 (66)

Type: Unscheduled DNA synthesis
Species: rat Sex: male
Strain:
Route of admin.: gavage
Exposure period: once
Doses: 100, 200, 500 mg/kg bw
Result:
Method:
Year: GLP:
Test substance:
Remark: positive control: 2,6-dinitrotoluene
The test material and the positive control were formulated
in corn oil for dosing.
Result: No induction of UDS was seen in the hepatocytes
17-APR-2001 (36)

5.7 Carcinogenicity

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5. Toxicity

Date: 17-APR-2001
ID: 99-08-1

5.8 Toxicity to Reproduction

Type: Fertility
Species: rat Sex: male/female

Strain: Wistar
Route of admin.: gavage
Exposure Period: 24 w
Frequency of treatment: once/d 5 d/w
Premating Exposure Period
male: 12 weeks
female: 12 weeks
Duration of test: 6 months
Doses: 300 mg/kg bw in olive oil
Control Group: yes, concurrent vehicle
Test substance: other TS: m-nitrotoluene; purity = 99%
Method: Males and females were dosed for 3 months before mating and during mating. 5 Treated males were mated with 5 treated females, 5 treated males were mated with 5 control females, five control males were mated with 5 control females, and 5 control males were mated with 5 treated females. Females were dosed during gestation. They were then maintained without treatment until 2 months after parturition, at which time they were dosed for another 4 weeks. Males were also held from mating until 2 months after parturition, at which time they were also dosed for another 4 weeks. A satellite group of 2 control females that were mated with control males were dosed during lactation only. The behavior, growth curve, and mortality of the parental animals were recorded. Blood samples were taken for clinical pathology and hematology, and all rats were killed at 3 months after parturition. Rats were given a gross necropsy examination and tissues were processed and examined histopathologically.

Year: GLP: no

Remarks: The protocol is not a standard study, but it is sufficient as a screening study for effects on fertility. There were no adverse effects on reproduction.

Result: No effect on reproductive parameters.
General parental toxicity: Alopecia, hemosiderosis and congestion in the spleen, a slight decrease in the level of hemoglobin, and a slight increase in methemoglobin. No effects were seen on fertility.
Toxicity to offspring: When the dams were exposed during gestation, similar spleen effects were seen in the offspring at 3 months of age but were much less significant than in the parental animals. When dams were treated during lactation only, the offspring had no histopathological changes in any organs at three months of age.

Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001 (38) (27)

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5. Toxicity

Date: 17-APR-2001
ID: 99-08-1

Type: Fertility
Species: mouse
Strain: B6C3F1

Sex: male/female

Route of admin.: oral feed
Exposure Period: 13 w
Frequency of treatment: daily
Duration of test:
Doses: 625,1250,2500,5000,10000 ppm (=ca. 101,187,375,750,1500 mg/kg bw)
Control Group: yes
Method: NTP program
Year: GLP:
Test substance:
Remark: 10 animals/sex/group
Result: no toxicity to reproduction system
17-APR-2001 (36) (37)

Type: Fertility
Species: rat Sex: male/female
Strain: other: F344/N
Route of admin.: oral feed
Exposure Period: 13 w
Frequency of treatment: daily
Duration of test:
Doses: 625,1250,2500,5000,10000 ppm (=ca. 47,94,188,375,750 mg/kg bw)
Control Group: yes
Method: NTP program
Year: GLP:
Test substance:
Remark: 10 rats/sex/group
Result: male, 10000 ppm: degeneration of the testes; reduction in sperm density, motility, and number, female, 10000 ppm: increased length of the estrous cycle
17-APR-2001 (36) (37)

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Date: 17-APR-2001
ID: 99-08-1

5. Toxicity

5.9 Developmental Toxicity/Teratogenicity

Species: rat Sex: male/female

Strain: Wistar
Route of admin.: gavage
Exposure period:
Frequency of treatment: daily, 5 days/week
Duration of test: 6 months
Doses: 300 mg/kg bw
Control Group: yes, concurrent vehicle
NOAEL Teratogen.: 300 mg/kg bw
Test substance: other TS: m-nitrotoluene; purity = 99%
Method: Males and females were dosed for 3 months before mating and during mating. 5 Treated males were mated with 5 treated females, 5 treated males were mated with 5 control females, five control males were mated with 5 control females, and 5 control males were mated with 5 treated females. Females were dosed during gestation. They were then maintained without treatment until 2 months after parturition, at which time they were dosed for another 4 weeks. Males were also held from mating until 2 months after parturition, at which time they were also dosed for another 4 weeks. A satellite group of 2 control females that were mated with control males were dosed during lactation only. The behavior, growth curve, and mortality of the parental animals were recorded. Blood samples were taken for clinical pathology and hematology, and all rats were killed at 3 months after parturition. Rats were given a gross necropsy examination and tissues were process and examined histopathologically.
Exposure period: 3 months before mating, during 3 weeks of mating, gestation, and from month 2 to month 3 after parturition for treated females; 3 months before mating, during 3 weeks of mating, and from month 2 to month 3 after parturition for treated males; during lactation only for two control group females.

Year: GLP: no
Remark: The protocol is not a standard study, but it is sufficient as a screening study for developmental effects. There was no selective effect on the offspring.

Result: Maternal general toxicity: Increased spleen size and weight. Accumulation of hemosiderin pigment in the spleen, a result of hemolysis, and a proliferation of erythroblasts, a sign of regeneration of the blood. Congestion of the spleen capillary sinus.
Pregnancy/litter data: All the females, controls and treated, delivered from 10 to 15 pups of normal vitality and behavior. Mortality in the newborn pups was the same for controls and treated. Offspring exposed during gestation had either accumulation of hemosiderin pigment in the spleen or a proliferation of erythroblasts three months after birth. Pups exposed only during lactation had no signs of toxicity at three months of age.

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Date: 17-APR-2001

5. Toxicity

ID: 99-08-1

Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
17-APR-2001

(38) (27)

5.10 Other Relevant Information

Type: Biochemical or cellular interactions
Remark: Addition of 2.5, 5.0, 7.5, 10.0 mM m-nitrotoluene to a suspension of sheep erythrocytes exhibited a dose dependent enhancement of methemoglobin formation.
Source: Bayer AG Leverkusen
19-FEB-1998 (67)

Type:
Remark: Investigation of methemoglobinemia in cats after i.p. injection; dose range: 100-500 mg/kg; slight methemoglobinemia and only few Heinz bodies, clotting time delayed
Source: Bayer AG Leverkusen
20-MAY-1994 (68)

Type:
Remark: Single dermal application of 1160 mg 3-MNT to a male rabbit resulted only in slight acceleration of the respiration rate, no further signs of intoxication were observed
Source: Bayer AG Leverkusen
20-MAY-1994 (69) (70)

Type:
Remark: Radioactivity was excreted by male rats 72 h after a single oral dose of 200 mg/kg labeled 3-nitrotoluene mainly in the urine (67.8 %; major metabolites: 3-nitrobenzoic acid, 3-acetamidobenzoic acid and 3-nitrohippuric acid), also in the feces (12.5 %) and in the expired air (0.1 %); total excretion: 80.4 % of dose
Source: Bayer AG Leverkusen
21-AUG-2000 (71) (65)

Type:
Remark: 12 h after application of a single oral dose of 200 mg/kg labeled 3-nitrotoluene to bile duct cannulated male and female rats metabolites were excreted in the urine (23.0 resp. 33.9 %, mainly 3-nitrobenzoic acid), the bile (10.8 resp. 4.3 %, mainly 3-nitrobenzoic acid) and the feces (0.4 resp. 0.2 %); total excretion: 34.2 resp. 37.6 % of dose
Source: Bayer AG Leverkusen
21-AUG-2000 (72) (73) (65)

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Date: 17-APR-2001

5. Toxicity

ID: 99-08-1

Type:
Remark: After a single oral dose of 200 mg/kg labeled 3-nitrotoluene to male rats radioactivity was covalently bound to hepatic macromolecules, maximum after 12 h; the

covalent binding to both total hepatic macromolecules and DNA was not effected by pretreatment with sulfotransferase inhibitors (PCP or DCNP)

Source: Bayer AG Leverkusen (74) (65)
21-AUG-2000

Type:
Remark: Incubation of freshly isolated rat hepatocytes with labeled 3-nitrotoluene dissolved in ethanol (no further information) resulted in 3 major metabolites: 3-nitrobenzoic acid, 3-nitrobenzyl alcohol and 3-nitrobenzyl alcohol glucuronide

Source: Bayer AG Leverkusen (75) (65)
21-AUG-2000

Type:
Remark: Addition of 3-nitrotoluene to isolated rat seminiferous tubules or sertoli cell cultures at concentrations of 1mmol, 10 umol, or 100 umol had no effect on basal or stimulated inhibin secretion; corresponding in vivo studies resulted in the death of the rats, but exposure to of the highest nonlethal dose (1 g/kg) had no significant effect either on spermatogenesis or on the levels of immunoactive inhibin in testicular interstitial fluid.

Source: Bayer AG Leverkusen (76) (77)
20-MAY-1994

Type:
Remark: Incubation of isolated hepatocytes from male F-344 rats with labeled 3-nitrotoluene resulted in forming 3-nitrobenzoic acid (45 %), 3-nitrobenzyl alcohol (9 %), 3-nitrobenzyl alcohol glucuronide (4 %)

Source: Bayer AG Leverkusen (78)
21-AUG-2000

Type:
Remark: Exposure of rats and mice for 4 hours to essentially saturated vapors of 3-nitrotoluene (157 and 151 ppm) resulted in no deaths and no lesions related to exposure; 14-day observation period

Source: Bayer AG Leverkusen (35)
20-MAY-1994

Type:
Remark: Contact of clipped trunks of female albino rabbits with undilute 3-nitrotoluene (dose level: 20 g/Kg) for 24 h does not produce observable toxic effects

Source: Bayer AG Leverkusen (35)
20-MAY-1994

5. Toxicity

Type:
Remark: Dermal application of 3-nitrotoluene to the tail of mice has little effect on respiration frequency or range of movement

Source: Bayer AG Leverkusen

20-MAY-1994

(79)

Type:

Remark: In vitro, nitrotoluol (isomer not specified) inhibited the oxygen utilization of V79 cells and drastically reduced the survival of the cells after radiation (2100 rad).

Source: Bayer AG Leverkusen

20-MAY-1994

(80)

Type:

Remark: Oral application of 3-NT to dogs resulted in inflammation of the digestive tract (no detailed information available)

Source: Bayer AG Leverkusen

20-MAY-1994

(81)

Type:

Remark: In cats or rabbits, inhalation of 0.2-0.25 mg nitrotoluene/l air (isomer not specified) for 10 hours did not induce any toxic effect.

Source: Bayer AG Leverkusen

20-MAY-1994

(82)

Type:

Remark: Dermal application of 50 cc nitrotoluene (isomer not specified) to the skin of a cat and a rabbit caused the death of the animals within 6 hours and 2.5 hours, respectively.

Source: Bayer AG Leverkusen

20-MAY-1994

(82)

Type:

Remark: Pseudomonas putitida F1 and Pseudomonas sp. strain JS150 and E. coli JM109(pDTG601) oxidize m-nitrotoluene to 3-nitrobenzyl alcohol.

Source: Bayer AG Leverkusen

21-AUG-2000

(83)

5.11 Experience with Human Exposure

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7. Risk Assessment

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7.1 End Point Summary

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7.2 Hazard Summary

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7.3 Risk Assessment

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